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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

APTALIS PHARMA US, INC. and APTALIS PHARMA CANADA ULC, Plaintiffs, vs. DELCOR ASSET CORPORATION, RENAISSANCE PHARMA, INC., and RENAISSANCE ACQUISITION HOLDINGS, LLC, Defendants.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Aptalis Pharma US, Inc. and Aptalis Pharma Canada ULC (collectively, "Aptalis"), by way of complaint against Defendants Delcor Asset Corporation, Renaissance Pharma, Inc., and Renaissance Acquisition Holdings, LLC (collectively, "Defendants") allege as follows:

Nature of the Action

This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by Defendants of Abbreviated New Drug Application No. 208362 ("ANDA" or "Defendants' ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic mesalamine suppositories prior to the expiration of U.S. Patent No. 7,541,384, U.S. Patent No. 8,217,083, and U.S. Patent No. 8,436,051.

Parties

1. Plaintiff Aptalis Pharma US, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054.

2. Plaintiff Aptalis Pharma Canada ULC is an unlimited liability corporation organized and existing under the Canada Business Corporations

Act, having a registered office at 4300 Bankers Hall West, 888 – 3rd Street S.W., Calgary, Alberta, T2P 5C5, Canada.

3. On information and belief, Defendant Delcor Asset Corporation ("Delcor") is a corporation organized and existing under the laws of Delaware, having a principal place of business in Lake Forest, Illinois.

4. On information and belief, Defendant Renaissance Pharma, Inc. ("Renaissance Pharma") is a corporation organized and existing under the laws of Delaware, having a principal place of business in Newtown, Pennsylvania. On information and belief, Renaissance Pharma is an affiliate of Delcor, and markets and sells prescription drugs in this District and throughout the United States.

5. On information and belief, Defendant Renaissance Acquisition Holdings, LLC ("Renaissance Holdings") is a corporation organized and existing under the laws of Delaware, having a principal place of business in Lake Forest, Illinois. On information and belief, Renaissance Holdings operates through its subsidiaries and affiliates, including Renaissance Pharma and Delcor, to market and sell prescription drugs in this District and throughout the United States.

Jurisdiction and Venue

6. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq*., including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338.

7. Defendants are subject to personal jurisdiction in this District because on information and belief, among other things, they have committed, or aided, abetted, induced, contributed to, and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to Aptalis in New Jersey.

8. This Court has personal jurisdiction over Defendants for additional reasons, including that, on information and belief, they regularly and systematically conduct business in New Jersey; and they have purposefully directed their activities at New Jersey and purposefully availed themselves of the laws of New Jersey through, among other things, registering as wholesale distributors of pharmaceutical products in New Jersey and the marketing, sales and/or distribution of pharmaceutical products in this District.

9. Defendants are further subject to personal jurisdiction in this District because on information and belief, Delcor and Renaissance Pharma, in

concert with, at the direction of, with the authorization of, and/or with the cooperation, participation and assistance of Renaissance Holdings, prepared and filed an ANDA with the FDA and sent notice of their paragraph IV certification to Aptalis in New Jersey. Defendants' act of filing their ANDA and sending notice of their paragraph IV certification provides sufficient minimum contacts with the State of New Jersey under a specific jurisdiction analysis.

10. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and/or 28 U.S.C. § 1400(b).

Factual Background

11. Aptalis and its affiliates manufacture and sell 1000 mg mesalamine rectal suppositories under the brand name CANASA® pursuant to New Drug Application ("NDA") No. 021252, which was approved by the FDA. CANASA® is approved for the treatment of active ulcerative proctitis.

12. U.S. Patent No. 7,541,384 ("the '384 patent") (attached as Exhibit A), titled "Mesalamine Suppository," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on June 2, 2009.

13. U.S. Patent No. 8,217,083 ("the '083 patent") (attached as Exhibit B), titled "Mesalamine Suppository," was duly and legally issued by the USPTO on July 10, 2012.

14. U.S. Patent No. 8,436,051 ("the '051 patent") (attached as Exhibit C), titled "Mesalamine Suppository," was duly and legally issued by the USPTO on May 7, 2013.

15. Aptalis owns all rights, title, and interest in and to the '384, '083 and '051 patents, including the right to sue and obtain relief for past, present, and future patent infringement.

16. Pursuant to 21 U.S.C. § 355(b)(1), the '083 and '051 patents are listed for CANASA® in the FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book").

17. On information and belief, Delcor and Renaissance Pharma, in concert with, at the direction of, with the authorization of, and/or with the cooperation, participation and assistance of Renaissance Holdings, prepared Defendants' ANDA and on or before November 10, 2015 submitted it to the FDA, pursuant to 21 U.S.C. § 355(j). Defendants' ANDA seeks FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic mesalamine 1000 mg rectal suppositories ("Defendants' Proposed Product").

18. Upon information and belief, Renaissance Pharma, in concert with, at the direction of, with the authorization of, and/or with the

cooperation, participation and assistance of Renaissance Holdings, has acted, and continues to act, as the agent of Delcor with regard to Defendants' ANDA, and will provide information and materials to the FDA in connection with Defendants' ANDA.

19. On information and belief, Defendants included in their ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV certification") that, in their opinion, the '083 and '051 patents are invalid, unenforceable and/or not infringed by Defendants' Proposed Product. On information and belief, Defendants sent Aptalis a notice letter stating that Defendants had included paragraph IV certifications in their ANDA with respect to the '083 and '051 patents, and that they are seeking approval of their ANDA prior to the expiration of the '083 and '051 patents.

Count I: Infringement of U.S. Patent No. 7,541,384

20. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 19 above.

21. On information and belief, Defendants prepared, submitted, and filed their ANDA with the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, marketing

and/or importation into the United States of Defendants' Proposed Product before the expiration of the '384 patent.

22. Under 35 U.S.C. § 271(e)(2)(A), Defendants infringed one or more claims of the '384 patent, in violation of Aptalis's patent rights, by submitting to the FDA an ANDA that seeks approval to commercially market Defendants' Proposed Product before the expiration of the '384 patent.

23. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Defendants' Proposed Product would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '384 patent under, for example, 35 U.S.C. § 271(a).

24. On information and belief, Defendants seek approval of the indication for Defendants' Proposed Product that is claimed in the '384 patent. Accordingly, if the FDA approves Defendants' ANDA, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' Proposed Product would contribute to or induce infringement, literally and/or through the doctrine of equivalents, of one or more claims of the '384 patent by users of Defendants' Proposed Product under, for example, 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

25. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will use Defendants'

Proposed Product in accordance with the label proposed in Defendants' ANDA, and Defendants will therefore induce infringement of one or more claims of the '384 patent, with the requisite intent.

26. On information and belief, Defendants were aware of the '384 patent prior to filing their ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants' Proposed Product in the United States.

27. On information and belief, Defendants have or will have knowledge that, if they were to receive approval from the FDA to market the Defendants' Proposed Product and make the Defendants' Proposed Product available for sale and/or use during its proposed shelf life before the expiration of the '384 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. On information and belief, Defendants had knowledge of that infringing use, and also that the Defendants' Proposed Product is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '384 patent.

28. Defendants' actions render this an exceptional case under 35 U.S.C. § 285.

29. If Defendants are permitted to manufacture, use, sell, offer for sale, market and/or import Defendants' Proposed Product into the United States, Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Defendants are enjoined by this Court.

Count II: Declaratory Judgment of Infringement Of U.S. Patent No. 7,541,384

30. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 29 above.

31. On information and belief, Defendants have taken significant and concrete steps toward infringement of the '384 patent under, for example, 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), including by submitting Defendants' ANDA for FDA approval of Defendants' Proposed Product, and by preparing to market and sell Defendants' Proposed Product.

32. If the FDA approves Defendants' ANDA and Defendants are permitted to manufacture, use, sell, offer for sale, market and/or import Defendants' Proposed Product into the United States, Defendants would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '384 patent under 35 U.S.C. § 271(a), in violation of Aptalis's patent rights.

33. On information and belief, Defendants seek approval of the indication for Defendants' Proposed Product that is claimed in the '384 patent. Accordingly, if the FDA approves Defendants' ANDA, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' Proposed Product would contribute to or induce the infringement, literally and/or through the doctrine of equivalents, of one or more claims of the '384 patent by users of Defendants' Proposed Product under, for example, 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

34. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will use Defendants' Proposed Product in accordance with Defendants' proposed label, and will therefore induce infringement of one or more claims of the '384 patent, with the requisite intent under 35 U.S.C. § 271(b).

35. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Aptalis and Defendants as to liability for Defendants' infringement of the '384 patent claims. Defendants' actions have created in Aptalis a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

36. On information and belief, Defendants were aware of the '384 patent prior to filing their ANDA seeking authorization to commercially

manufacture, use, offer for sale, and sell Defendants' Proposed Product in the United States.

37. On information and belief, Defendants have or will have knowledge that, if they were to receive approval from the FDA to market the Defendants' Proposed Product and make the Defendants' Proposed Product available for sale and/or use during its proposed shelf life before the expiration of the '384 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. On information and belief, Defendants had knowledge of that infringing use, and also had knowledge that the Defendants' Proposed Product is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '384 patent.

38. Defendants' actions render this an exceptional case under 35 U.S.C. § 285.

39. Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Defendants are enjoined by this Court.

Count III: Infringement of U.S. Patent No. 8,217,083

40. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 39 above.

41. On information and belief, Defendants prepared, submitted, and filed their ANDA with the FDA under § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, marketing and/or importation into the United States of Defendants' Proposed Product before the expiration of the '083 patent.

42. On information and belief, Defendants included in their ANDA a paragraph IV certification that, in their opinion, the '083 patent is invalid, unenforceable and/or not infringed by Defendants' Proposed Product.

43. Under 35 U.S.C. § 271(e)(2)(A), Defendants infringed one or more claims of the '083 patent, in violation of Aptalis's patent rights, by submitting to the FDA an ANDA that seeks approval to commercially market Defendants' Proposed Product before the expiration of the '083 patent.

44. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' Proposed Product would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '083 patent under, for example, 35 U.S.C. § 271(a).

45. On information and belief, Defendants seek approval of the indication for Defendants' Proposed Product that is claimed in the '083 patent. Accordingly, if the FDA approves Defendants' ANDA, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' Proposed Product would contribute to or induce the infringement, literally and/or through the doctrine of equivalents, of one or more claims of the '083 patent by users of Defendants' Proposed Product under, for example, 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

46. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will use Defendants' Proposed Product in accordance with Defendants' proposed label, and Defendants will therefore induce infringement of one or more claims of the '083 patent, with the requisite intent under 35 U.S.C. § 271(b).

47. On information and belief, Defendants were aware of the '083 patent prior to filing their ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants' Proposed Product in the United States.

48. On information and belief, Defendants have or will have knowledge that, if they were to receive approval from the FDA to market the Defendants' Proposed Product and make the Defendants' Proposed Product

available for sale and/or use during its proposed shelf life before the expiration of the '083 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. On information and belief, Defendants had knowledge of that infringing use, and also that the Defendants' Proposed Product is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '083 patent.

49. Defendants' actions render this an exceptional case under 35 U.S.C. § 285.

50. If Defendants are permitted to manufacture, use, sell, offer for sale, market and/or import Defendants' Proposed Product into the United States, Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Defendants are enjoined by this Court.

Count IV: Declaratory Judgment Of Infringement Of U.S. Patent No. 8,217,083

51. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 50 above.

52. On information and belief, Defendants have taken significant and concrete steps toward infringement of the '083 patent under, for example, 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), including by

submitting Defendants' ANDA for FDA approval of Defendants' Proposed Product, and by preparing to market and sell Defendants' Proposed Product.

53. If the FDA approves Defendants' ANDA and Defendants are permitted to manufacture, use, sell, offer for sale, market and/or import Defendants' Proposed Product into the United States, Defendants would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '083 patent under 35 U.S.C. § 271(a), in violation of Aptalis's patent rights.

54. On information and belief, Defendants seek approval of the indication for Defendants' Proposed Product that is claimed in the '083 patent. Accordingly, if the FDA approves Defendants' ANDA, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' Proposed Product would contribute to or induce the infringement, literally and/or through the doctrine of equivalents, of one or more claims of the '083 patent by users of Defendants' Proposed Product under, for example, 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

55. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will use Defendants' Proposed Product in accordance with Defendants' proposed label, and will

therefore induce infringement of one or more claims of the '083 patent, with the requisite intent under 35 U.S.C. § 271(b).

56. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Aptalis and Defendants as to liability for Defendants' infringement of the '083 patent claims. Defendants' actions have created in Aptalis a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

57. On information and belief, Defendants were aware of the '083 patent prior to filing their ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants' Proposed Product in the United States.

58. On information and belief, Defendants have or will have knowledge that, if they were to receive approval from the FDA to market the Defendants' Proposed Product and make the Defendants' Proposed Product available for sale and/or use during its proposed shelf life before the expiration of the '083 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. On information and belief, Defendants had knowledge of that infringing use, and also that the Defendants' Proposed Product is not a staple article or commodity of

commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '083 patent.

59. Defendants' actions render this an exceptional case under 35 U.S.C. § 285.

60. Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Defendants are enjoined by this Court.

Count V: Infringement Of U.S. Patent No. 8,436,051

61. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 60 above.

62. On information and belief, Defendants prepared, submitted, and filed their ANDA with the FDA under § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, marketing and/or import into the United States of Defendants' Proposed Product before the expiration of the '051 patent.

63. On information and belief, Defendants included in their ANDA a paragraph IV certification that, in their opinion, the '051 patent is invalid, unenforceable and/or not infringed by Defendants' Proposed Product.

64. Under 35 U.S.C. § 271(e)(2)(A), Defendants infringed one or more claims of the '051 patent, in violation of Aptalis's patent rights, by submitting

to the FDA an ANDA that seeks approval to commercially market Defendants' Proposed Product before the expiration of the '051 patent.

65. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' Proposed Product would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '051 patent under, for example, 35 U.S.C. § 271(a).

66. On information and belief, Defendants seek approval of the indication for Defendants' Proposed Product that is claimed in the '051 patent. Accordingly, if the FDA approves Defendants' ANDA, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' Proposed Product would contribute to or induce the infringement, literally and/or through the doctrine of equivalents, of one or more claims of the '051 patent by users of Defendants' Proposed Product under, for example, 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

67. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will use Defendants' Proposed Product in accordance with Defendants' proposed label, and Defendants will therefore induce infringement of one or more claims of the '051 patent, with the requisite intent under 35 U.S.C. § 271(b).

68. On information and belief, Defendants were aware of the '051 patent prior to filing their ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants' Proposed Product in the United States.

69. On information and belief, Defendants have or will have knowledge that, if Defendants were to receive approval from the FDA to market the Defendants' Proposed Product and make the Defendants' Proposed Product available for sale and/or use during its proposed shelf life before the expiration of the '051 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. On information and belief, Defendants had knowledge of that infringing use, and also that the Defendants' Proposed Product is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '051 patent.

70. Defendants' actions render this an exceptional case under 35 U.S.C. § 285.

71. If Defendants are permitted to manufacture, use, sell, offer for sale, market and/or import Defendants' Proposed Product into the United States, Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Defendants are enjoined by this Court.

Count VI: Declaratory Judgment of Infringement Of U.S. Patent No. 8,436,051

72. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 71 above.

73. On information and belief, Defendants have taken significant and concrete steps toward infringement of the '051 patent under, for example, 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), including by submitting Defendants' ANDA for FDA approval of Defendants' Proposed Product, and by preparing to market and sell Defendants' Proposed Product.

74. If the FDA approves Defendants' ANDA and Defendants are permitted to manufacture, use, sell, offer for sale, market and/or import Defendants' Proposed Product into the United States, Defendants' would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '051 patent under 35 U.S.C. § 271(a), in violation of Aptalis's patent rights.

75. On information and belief, Defendants seek approval of the indication for Defendants' Proposed Product that is claimed in the '051 patent. Accordingly, if the FDA approves Defendants' ANDA, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' Proposed Product would contribute to or induce the

infringement, literally and/or through the doctrine of equivalents, of one or more claims of the '051 patent by users of Defendants' Proposed Product under, for example, 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

76. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will use Defendants' Proposed Product in accordance with Defendants' proposed label, and will therefore induce infringement of one or more claims of the '051 patent, with the requisite intent under 35 U.S.C. § 271(b).

77. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Aptalis and Defendants as to liability for Defendants' infringement of the '051 patent claims. Defendants' actions have created in Aptalis a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

78. On information and belief, Defendants were aware of the '051 patent prior to filing their ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants' Proposed Product in the United States.

79. On information and belief, Defendants have or will have knowledge that, if they were to receive approval from the FDA to market the Defendants' Proposed Product and make the Defendants' Proposed Product

available for sale and/or use during its proposed shelf life before the expiration of the '051 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. On information and belief, Defendants had knowledge of that infringing use, and also that the Defendants' Proposed Product is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '051 patent.

80. Defendants' actions render this an exceptional case under 35 U.S.C. § 285.

81. Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Defendants are enjoined by this Court.

Prayer For Relief

Wherefore, Aptalis respectfully requests the following relief:

A. Judgment that Defendants have infringed or will infringe one or more claims of the '384, '083, and '051 patents;

B. Judgment that the claims of the '384, '083, and '051 patents are valid and enforceable;

C. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendants' ANDA under § 505(j) of the Federal

Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration dates of the '384, '083 and '051 patents, including any extensions or exclusivities;

D. A declaratory judgment that Defendants would infringe one or more claims of the '384, '083 and/or '051 patents if they manufacture, use, sell, offer to sell, market and/or import into the United States Defendants' Proposed Product prior to the expiration of the '384, '083 and '051 patents, including any extensions or exclusivities;

E. A declaratory judgment that the commercial manufacture, use, sale, offer for sale and/or importation in the United States of Defendants' Proposed Product by Defendants would induce and/or contribute to third-party infringement of the '384, '083 and '051 patents;

F. Pursuant to 35 U.S.C. § 271(e)(4)(B), an injunction restraining and enjoining Defendants and their officers, agents, attorneys and employees, and those acting in privity or concert with Defendants, from engaging in the commercial manufacture, use, offer for sale, sale, marketing and/or importation into the United States, of Defendants' Proposed Product as claimed in one or more claims of the '384, '083 and/or '051 patents, until the expiration dates of the '384, '083 and '051 patents, including any extensions or exclusivities;

G. If Defendants commercially make, use sell, or offer to sell Defendants' Proposed Product within the United States, or import Defendants' Proposed Product into the United States, prior to the expiration of any one of the '384, '083 and '051 patents, including any extensions or exclusivities, that Aptalis be awarded monetary damages for those infringing acts to the fullest extent allowed by law, and be awarded prejudgment interest based on those monetary damages;

H. Judgment that Defendants' infringement of the '384, '083 and '051 patents based on their ANDA would be willful if Defendants commercially manufacture, use, sell, offer to sell and/or import any products that are the subject of their ANDA prior to the expiration of the '384, '083 and '051 patents.

I. Judgment that this is an exceptional case and that Aptalis is entitled to its reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

J. The costs and expenses of this action; and

K. Such other and further relief as the Court may deem just and proper.

Dated: December 23, 2015 Respectfully submitted,

By: /s David E. De Lorenzi

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